



49076.000004.UTL2  
U.S. PATENT

UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of	)	Group Art Unit: 1642
LEDBETTER	)	Examiner: Helms, Larry Ronald
Serial No.: 10/053,530	)	Confirmation No.: 8993
Filed: January 17, 2002	)	
For: BINDING DOMAIN	)	
IMMUNOGLOBULIN FUSION	)	
PROTEINS	)	

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)(3)

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In compliance with Applicant's duty under 37 C.F.R. § 1.97-98, the following information is brought to the attention of the Examiner. The items are listed on the attached form PTO/SB/08 and copies are enclosed for the convenience of the Examiner. Please note, some of the references listed on the accompanying PTO/SB/08 form have come to applicant's attention in a communication from a foreign patent office (International Search Report attached hereto, as well as a European Search Report) in a counterpart foreign application. Applicant is submitting the International Search Report and the European Search Report from the International Searching Authorities for this purpose.

The items identified in this Information Disclosure Statement may or may not be "material" pursuant to 37 C.F.R. § 1.56 and the submission thereof by Applicant shall not be construed as an admission that any such patent, publication or other information referred to

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therein is material or considered to be material (37 C.F.R. § 1.97(h)), or even qualified as "prior art" under 35 U.S.C. § 102 with respect to this invention unless specifically designated by Applicant as such.

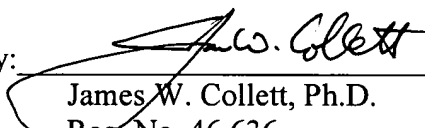
The attached Information Disclosure Statement is being filed in accordance with 37 CFR §§ 1.97(c) and 1.98. This Information Disclosure Statement is being filed after an action on the merits but before a Final Action under § 1.113 or a Notice of Allowance under § 1.113.

The fee of \$180.00, pursuant to 37 CFR § 1.17(p) is due in connection with this filing. The Commissioner is authorized to debit this amount and any additional fees required by this paper or credit any overpayment to Deposit Account No. 02-4553.

Respectfully submitted,

BUCHANAN INGERSOLL L.L.P.

By:

  
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06-07-04

DPO/21 GP1642  
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PTO/SB/21 (02-04)

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**TRANSMITTAL  
FORM**

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

26

Application Number	10/053,530
Filing Date	January 17, 2002
First Named Inventor	LEDBETTER
Art Unit	1642
Examiner Name	Helms, Larry Ronald
Attorney Docket Number	49076.000004.UTL2

**ENCLOSURES (Check all that apply)**

- |  |   |   |
|--|---|---|
| <input checked="" type="checkbox"/> Fee Transmittal Form                     | <input type="checkbox"/> Drawing(s)   | <input type="checkbox"/> After Allowance communication to Technology Center (TC)        |
| <input type="checkbox"/> Fee Attached  | <input type="checkbox"/> Licensing-related Papers                                       | <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences     |
| <input type="checkbox"/> Amendment/Reply                                     | <input type="checkbox"/> Petition   | <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) |
| <input type="checkbox"/> After Final   | <input type="checkbox"/> Petition to Convert to a Provisional Application               | <input type="checkbox"/> Proprietary Information  |
| <input type="checkbox"/> Affidavits/declaration(s)                           | <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address | <input type="checkbox"/> Status Letter  |
| <input type="checkbox"/> Extension of Time Request                           | <input type="checkbox"/> Terminal Disclaimer  | <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):         |
| <input type="checkbox"/> Express Abandonment Request                         | <input type="checkbox"/> Request for Refund   | PTO/SB/08A (5 pages); 71 references; Return Postcard                                    |
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| <input type="checkbox"/> Response to Missing Parts/Incomplete Application    |   |   |
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**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm or Individual name	James W. Collett, Ph.D.
Signature	
Date	May 24, 2004

**CERTIFICATE OF TRANSMISSION/MAILING**

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

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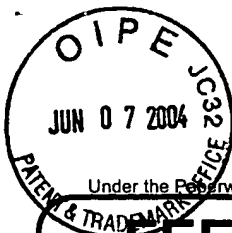
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This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PTO/SB/17 (10-03)

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# FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT

(\$)180.00**Complete if Known**

Application Number	10/053,530
Filing Date	1/17/02
First Named Inventor	LEDBETTER
Examiner Name	HELMG
Art Unit	1642
Attorney Docket No.	49076.000004.072.2

**METHOD OF PAYMENT** (check all that apply)☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None☒ Deposit Account:Deposit Account Number: 02-4553  
Deposit Account Name: BUCHANAN INGERSOLL P.C.

The Director is authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☒ Credit any overpayments☒ Charge any additional fee(s) or any underpayment of fee(s)☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.**FEE CALCULATION****1. BASIC FILING FEE**

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) (\$)

**2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE**

	Total Claims	Extra Claims	Fee from below	Fee Paid
Independent Claims		-20** =	X	
Multiple Dependent		-3** =	X	

Large Entity		Small Entity		Fee Description
Fee Code	Fee (\$)	Fee Code	Fee (\$)	
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$)

\*\*or number previously paid, if greater; For Reissues, see above

**FEE CALCULATION** (continued)**3. ADDITIONAL FEES**

Large Entity Small Entity

Fee Code	Fee (\$)	Fee Code	Fee (\$)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for <i>ex parte</i> reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	180.00
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify)

\*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$)

180.00

**SUBMITTED BY**

Name (Print/Type)	JAMES W. COLLETT, Ph.D.	Registration No. (Attorney/Agent)	46,636	Telephone	(819) 578-5000
Signature	J. W. Collett	Date	5-24-04		

(Complete if applicable)

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This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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		<b>Application Number</b>	10/053,530		
		<b>Filing Date</b>	1/17/02		
		<b>First Named Inventor</b>	Ledbetter		
		<b>Group Art Unit</b>	1642		
		<b>Examiner Name</b>	Helms		
<b>Sheet</b>	1	<b>of</b>	5	<b>Attorney Docket Number</b>	49076.000004.UTL2

U. S. PATENT DOCUMENTS						
Examine Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	A.	5,098,833		LASKY et al.	03/24/92	
	B.	5,260,203		LADNER et al.	11/09/93	
	C.	5,434,131		LINSLEY et al.	07/18/95	
	D.	5,455,030		LADNER et al.	10/03/95	
	E.	5,521,288		LINSLEY et al.	05/28/96	
	F.	5,580,756		LINSLEY et al.	12/03/96	
	G.	5,605,690		JACOBS et al.	02/25/97	
	H.	5,637,481		LEDBETTER et al.	06/10/97	
	I.	5,709,859		ARUFFO et al.	01/20/98	
	J.	5,714,147		CAPON et al.	02/03/98	
	K.	5,770,197		LINSLEY et al.	06/23/98	
	L.	5,773,253		LINSLEY et al.	06/30/98	
	M.	5,844,095		LINSLEY et al.	12/01/98	
	N.	5,869,049		NOELLE et al.	02/9/99	
	O.	5,876,718		NOELLE et al.	03/02/99	
	P.	5,916,560		LARSEN et al.	06/29/99	
	Q.	6,087,329		ARMITAGE et al.	07/11/00	
	R.	6,090,914		LINSLEY et al.	07/18/00	
	S.	6,194,551 B1		IDUSOGIE et al.	02/27/01	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document by the two-letter code (WPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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<b>Examiner Signature</b>		<b>Date Considered</b>	
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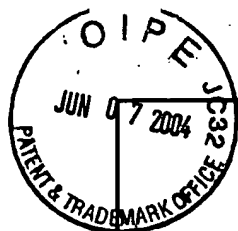
Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		<b>Complete if Known</b>			
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Sheet	2	of	5	Attorney Docket Number	49076.000004.UTL2

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	T.	6,264,951 B1		ARMITAGE et al.	07/24/01	
	U.	6,312,692 B1		NOELLE et al.	11/06/01	
	V.	6,376,459 B1		ARUFFO et al.	04/23/02	
	W.	6,384,198 B1		DIEGEL et al.	05/07/02	
	X.	6,410,319 B1		RAUBITSCHKE et al.	06/25/02	
	Y.	6,444,792 B1		GRAY et al.	09/03/02	
	Z.	6,472,510 B1		ARUFFO et al.	10/29/02	
	AA.	6,623,940 B1		LEDBETTER et al.	09/23/03	
	AB.	6,641,809 B1		LINSLEY et al.	11/04/03	
	AC.	2001/004135 A1		STAHL et al.	11/22/01	
	AD.	2002/0031510 A1		LARSEN et al.	03/14/02	
	AE.	2002/0039557 A1		WHITE	04/04/02	
	AF.	2002/0155604 A1		LEDBETTER et al.	10/24/02	
	AG.	2003/0219436 A1		LEDBETTER et al.	11/27/03	
	AH.	2003/0219446 A1		LINSLEY et al.	11/27/03	
	AI.	2003/0219876 A1		LEDBETTER et al.	11/27/03	
	AJ.	2004/0058445 A1		LEDBETTER et al.	03/25/04	

FOREIGN PATENT DOCUMENTS								
Examine Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup> known)	Kind Code <sup>5</sup>	Number <sup>4</sup> (if				
	AK.	WC	92/00092		BRISTOL-MYERS SQUIBB COMPANY	01/09/92		
	AL	WC	93/00431		BRISTOL-MYERS SQUIBB COMPANY	01/07/93		
	AM	WC	99/42077		XCYTE THERAPIES, INC.	08/26/99		

Examiner Signature		Date Considered	
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				<b>Complete if Known</b>	
				<b>Filing Date</b>	1/17/02
				<b>First Named Inventor</b>	Ledbetter
				<b>Group Art Unit</b>	1642
				<b>Examiner Name</b>	Helms
<b>Sheet</b>	3	of	5	<b>Attorney Docket Number</b>	49076.000004.UTL2

/	AN	EP	0 555 880 A2		BRISTOL-MYERS SQUIBB COMPANY	08/18/93		
/	AO	EP	0 757 099 A2		BRISTOL-MYERS SQUIBB COMPANY	07/21/95		
/	AP	EP	0 682 039 A1		BRISTOL-MYERS SQUIBB COMPANY	11/15/95		
/	AQ	EP	1 186 300 A1		BRISTOL-MYERS SQUIBB COMPANY			

#### OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		AICHER, et al., "Characterization of Human Inducible Costimulator Ligand Expression and Function", The Journal of Immunology, 2000, 164: 4689-4696	
		CARTER, "Improving the Efficacy of Antibody-Based Cancer", Nature, November 2001, Volume 1, 118-129	
		CLARK et al., "Structure, Function, and Genetics of Human B Cell-Associated Surface Molecules", Advances in Cancer Research, Vol. 52, 81-149	
		DAMLE, et al., "Direct helper T cell-induced B cell differentiation involves interaction between T cell antigen CD28 and B cell activation antigen B7", Eur. J. Immunology 1991; 21; 1277-1282	
		DAVIES, et al., "'Camelising' Human Antibody Fragments: NMR Studies on VH Domains," FEBS Letters 339 (1994) 285-290	
		DESMYTER et al., "Crystal structure of a camel single-domain V <sub>H</sub> antibody fragment in complex with lysozyme", Nature Structural Biology, Volume 3, Number 9, September 1996, 803-811	
		DIETSCH et al., "Coengagement of CD2 with LFA-1 or VLA-4 by bispecific ligand fusion proteins primes T cells to respond more effectively to T cell receptor-dependent signals, Journal of Leukocyte Biology, Volume 56, October 1994, 444-452	
		DIETSCH et al., "Bispecific receptor globulins, novel tools for the study of cellular interactions", Journal of Immunological Methods, 162 (1993) 123-132	
		DURIE et al., "Prevention of Collagen-Induced Arthritis with an Antibody to gp39, the Ligand for CD40", Science, Vol. 261, September 3, 1993, 1328-1330	

<b>Examiner Signature</b>		<b>Date Considered</b>	
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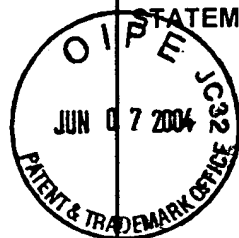


INFORMATION DISCLOSURE STATEMENT BY APPLICANT  (use as many sheets as necessary)			Complete if known		
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Sheet	4	5	Attorney Docket Number	49076.000004.UTL2	

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
		FELL et al., "Genetic Construction and Characterization of a Fusion Protein Consisting of a Chimeric F(ab') with Specificity for Carcinomas and Human IL-2", The Journal of Immunology, Vol. 146, 2446-2452, No. 7, April 1, 1991		
		FILPULA et al., "Single-chain Fv designs for protein, cell and gene therapeutics" Exp. Opin. Ther. Patents (1999) 9 (3):231-245		
		GILLILAND et al., "Rapid and Reliable Cloning of antibody Variable Regions and Generation of Recombinant Single Chain Antibody Fragments", Tissue Antigens 1996: 47: 1-20 (Denmark)		
		HAYDEN, et al., "Antibody Engineering," Curr. Opin. Immuno., 9:201-212 (1997)		
		HAYDEN, et al., "Single-chain Mono- and bispecific Antibody Derivatives With Novel Biological Properties and Antitumor Activity from a COS Cell Transient Expression System," Thera. Immuno., 1:3-15 (1994)		
		HAYDEN et al., "Costimulation by CD28 sFv expressed on the tumor cell surface or as a soluble bispecific molecule targeted to the L6 carcinoma antigen", Tissue Antigens 1996: 48; 242-254		
		HU, et al., "Minibody: A Novel Engineered Anti-Carcinoembryonic Antigen Antibody Fragment (Single-Chain Fv-CH3) Which Exhibits Rapid, High-Level Targeting of Xenografts," Cancer Res. 56(13):3055-3061 (1996)		
		HUDSON, "Recombinant antibodies: a novel approach to cancer diagnosis and therapy", Exp. Opin. Invest. Drugs (2000) 9(6):1231-1242		
		HUDSON, "Recombinant antibody fragments", Current Opinion in Biotechnology, 1998, 9:395-402		
		KORTT, et al., "Dimeric and Trimeric Antibodies: High Avidity scFvs for Cancer Targeting," Biomole. Eng., 18:95-108 (2001)		
		LEE et al., "Generation and characterization of a novel single-gene-encoded single-chain immunoglobulin molecule with antigen binding activity and effector functions", Molecular Immunology 36 (1999) 61-71		
		LI, et al., "Single-chain antibodies against human insulin-like growth factor I receptor: expression, purification and effect on tumor growth", Cancer Immunol. Immunother (2000) 49:243-252		

Examiner Signature		Date Considered	
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Substitute for form 1449B/PTO		<b>Complete if known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		<b>Application Number</b>	10/053,530
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<b>Sheet</b>	5		5
		<b>Attorney Docket Number</b>	49076.000004.UTL2

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		LIU, et al., "Production of a Mouse-Human Chimeric Monoclonal Antibody to CD20 With Potent Fc-Dependent Biological Activity," <i>J. Immunol.</i> 139(10):3521-3526 (1987)	
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<b>Examiner Signature</b>		<b>Date Considered</b>	
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